Congress of the United States
Washington, DC 20510

March 10, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Tavenner:

We write to express our concern regarding continued difficulties experienced by Medicare beneficiaries when appealing denials of coverage for prescription drugs. We ask that you take the steps enumerated below to improve beneficiary access to needed medications, particularly life-saving specialty drug products.

First, the availability of Part D appeals data is limited at best, particularly with regards to denials at the pharmacy counter, coverage determinations, and redeterminations. What data are available capture only those appeals that reach review by the Independent Review Entity (IRE)—the third formal tier of the appeals process, and the first time that a beneficiary appeal is reviewed by an entity other than a drug plan. It remains unclear how many beneficiaries are able to successfully complete the appeals process at the plan level, leaving us with no way to tell how many beneficiaries must cope with delayed or limited access to prescribed medications.

What limited information is available on Part D exceptions and appeals is not reassuring. The agency's 2012 audit suggests that Part D plans struggle most with managing coverage determinations, appeals, and grievances.[1] Additionally, 2011 data released by the agency finds that over half (54%) of plan-level denials are overturned by the IRE.[2] This rate of reversals by the IRE, coupled with the agency's own audit data on plans, raises serious questions about how well the redetermination and appeals process is

[1] Sokolovsky, J., Shinobu, S. and L. Metayer, "Part D exceptions and appeals," (Presentation to MedPAC: September 2013), available at: http://www.medpac.gov/transcripts/part%20d%20exceptions%20&%20appeals.pdf

[2] Excludes cases that were dismissed, withdrawn or remanded and cases involving non-Part D drugs, see: Centers for Medicare and Medicaid Services, "Part D Fact Sheets CY 2011" (2011), available at: http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html

working, and transparency is needed. Therefore, in response to this letter, we ask that you provide us with a meaningful analysis of updated plan-level appeals data for the most recent year available.

Second, in the case of high-cost medications placed on the specialty tier, a specific type of coverage determination—a tiering exception, in which an enrollee can request a non-preferred drug at the lower cost-sharing terms applicable to drugs in a preferred tier—is not permitted. For drugs in a specialty tier, requests for such exceptions are categorized as a "grievance" rather than an official coverage determination. This leads to distorted—and in many cases absent information about access to specialty prescription drugs. We ask that you re-categorize requests for a tiering exception on the specialty tier as a coverage determination.

Third, beneficiary notification of non-coverage is not consistent across federal health programs. In traditional Medicare, Medicaid, and Medicare Advantage, a beneficiary receives a notice of non-coverage after a service is received or prior to the service, because it is not authorized. In Part D, however, beneficiaries are expected to formally request notice of non-payment after refusal of a service, rather than initiating a coverage determination when the prescription is presented. Treating the presentation of the prescription at the pharmacy counter as a request for a coverage determination would allow beneficiaries to more easily navigate situations where a prescribed medication is denied.

Finally, the agency has retained a $600 per month cost threshold for drugs placed on a specialty tier for the last six years, and in the draft 2015 Medicare Part C and D call letter, proposes to leave this threshold in place for a seventh year. Given the rising costs of life-saving drug treatments, $600 is quite a low threshold compared to several years ago and further, is not necessarily representative of the most expensive or unique items. Maintaining this level without adjustment will allow an increasing number of drugs to be placed on the specialty tier. Indeed, the number of drugs being placed on this tier of plans' formularies has increased over 90 percent since 2006.[3] We ask that you revise and update the methodology for the specialty tier threshold in the final 2015 Medicare Part C and Part D call letter, or, at the very least, further evaluate the composition and growth of drugs over the past several years that have been placed on the specialty tier. If beneficiaries are to have their appeal rights restricted for these drugs, then the tier should only reflect truly high-cost and unique items.

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[3] Medicare Patients' Access Rx Coalition. Revising Specialty Tiers: Protecting Medicare Part D Beneficiaries from Burdensome Cost Sharing. White Paper, July, 2013.

The Medicare Part D appeals process should be transparent, easy-to-understand, and fair in order for it to function as a true recourse for beneficiaries. Denials of needed medications may be unavoidable, but a streamlined and transparent appeals process would mitigate much of the existing confusion and hardship felt by beneficiaries. We look forward to working with you on this very important issue.

Sincerely,

Bill Nelson
U.S. Senator

Susan M. Collins
U.S. Senator

Henry C. "Hank" Johnson
U.S. Representative

Jan Schakowsky
U.S. Representative

David B. McKinley, P.E.
U.S. Representative

Keith Ellison
U.S. Representative